REMARKS

In view of the remarks put forth below, reconsideration and allowance of the claims of the subject application are respectfully requested.

Formal Matters

The specification has been amended on page 47 to remove an embedded hyperlink.

No new matter has been added.

Specification

The specification on page 47 has been objected to for use of an embedded hyperlink. The specification has been amended on page 47 such that the website address noted is not an embedded hyperlink (i.e., will not be a live hyperlink upon online publication). Accordingly, this objection may be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph (Enablement)

Claims 1, 2, 9-11 and 19-24 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement.

With regard to enablement, MPEP §2164.01 states the following:

> Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims of the subject application are drawn to nucleic acids present in other than its natural environment having a sequence identity of at least 95% with SEQ ID

NO:17 and encoding a chromo- or fluorescent protein (as well as cells, vectors and kits containing such nucleic acids).

The Examiner acknowledges that the claims drawn to SEQ ID NO: 17 are enabled by the specification, but asserts that nucleic acids 95% identical to SEQ ID NO: 17 encoding a chromo- or fluorophore are not enabled by the specification.

The Applicants respectfully disagree.

As indicated above, a claimed invention is enabled by the specification if the experimentation is not "undue", even if experimentation is required. Practitioners in the chemical and molecular biology arts frequently engage in extensive experimentation where many factors must be varied to succeed in performing an experiment or in producing a desired result. The Federal Circuit has found that such extensive experimentation is not undue in the molecular biology arts, concluding that extensive screening experiments, while being voluminous, are not undue because those in the art routinely perform such experimentation.

For example, in Hybritech v. Monoclonal Antibodies, Inc. 231 USPQ 81 (Fed. Cir. 1986), the court made the following statement with regard to the level of experimentation required to practice the scope of a claimed invention and enablement:

> The claimed compositions recite isolated polypeptides with 60% or more sequence identity to SEQ ID NO:3 that suppress proliferation of lympho-hematopoietic cells. The only experiments, if any, that need be performed to enable the entire scope of the claim are those designed to determine which sequences retain the ability to suppress proliferation of lympho-hematopoietic cells. The sequence of polypeptides retaining biological activity is determined through routine experimentation that is empirical in nature, typically employing nothing more than performing the same assay disclosed in the specification on a variety of sequence variants of the polypeptide made by routine recombinant DNA techniques. Since these experiments are empirical in nature, no undue experimentation is required. In other words, the only experimentation that may be required to enable the claimed invention are those experiments to determine the presence of a certain activity, and since this only requires a routine assay on polypeptide variants to determine the active variants, no undue experimentation is necessary.

As is clear from this excerpt, the position of the courts is that claims drawn to biopolymeric sequences having a percentage similarity to a reference sequence that have a clearly defined functional property are enabled as long as the experimentation required is of an empirical nature, requiring "*nothing more than performing the same assay disclosed in the specification on a variety of sequence variants of the polypeptide made by routine recombinant DNA techniques*". The Applicants contend that, similar to the case cited above, the claimed invention is fully enabled because the specification provides assays for producing and determining the chromo- and fluorogenic characteristics of a protein encoded by the claimed nucleic acids (see, e.g., the Experimental section starting on page 45 and Figures 4 and 6). As such, the claimed invention is fully enabled by the specification.

In other words, the Applicants submit that it requires nothing more than empirical experimentation using routine recombinant DNA techniques and assays disclosed in the specification (i.e., to determining the chromo- or fluorescent properties of a protein encoded by the claims nucleic acids) to practice the claimed invention.

Contrary to the Examiner's assertion, the Applicants submit that enablement of the claimed invention is not dependent on whether there is uncertainty regarding how a specific change in the nucleotide sequence of SEQ ID NO: 17 would impact the chromo- or fluorophore properties of the encoded protein. As is clear from the discussion above, this is not the test for enablement. Rather, enablement is based on whether undue experimentation is required to practice the claimed invention. Because the teachings of the specification (e.g., how to produce and assess the chromo- and fluorophore properties of a protein encoded by SEQ ID NO:17) coupled with routine DNA recombinant techniques engaged in by those in the art is all that is required to practice the claimed invention, practicing the claimed invention does not require undue experimentation.

As such, the Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph (Written Description)

Claims 1, 2, 9-11 and 19-24 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description.

In making this rejection, the Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to convey to one of ordinary in the art that the inventors had possession of the invention.

Applicants submit that the specification provides ample written description support for the claimed invention.

See, for example, the specification at page 15, lines 10-20, which describes nucleic acids having sequence similarity to SEQ ID NO: 17.

The specification also provides clear written description support for subcloning polynucleotides encoding chromo- and fluorophore proteins as well as their subsequence isolation and analysis (see, e.g., the Experimental section and Figures). The specification specifically demonstrates the chromo-/fluorophore properties of a protein encoded by SEQ ID NO: 17 (see mcavGFP in Figures 4 and 6).

In view of the abundant written description support for the claimed invention, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone Bret Field at 650-327-3400.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815.

Respectfully submitted,
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